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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/887,493 | 06/22/2001 | Gregor Cevc | 500.1013 | 7718 |

7590 11/04/2003

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/887,493 | CEVC, GREGOR | |
| | Examiner | Art Unit | |
| | Susan Coe | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,12-14,21-24,35,39-41,44-46 and 51-85 is/are pending in the application.
- 4a) Of the above claim(s) 52,53,55-75 and 77-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,12-14,21-24,35,39-41,44-46,51,54,76 and 83-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 17, 2003 has been entered.
2. Claims 8, 10, 11, 15-20, 25-34, 36-38, 42, 43, 47-50 have been cancelled.
3. Claims 83, 84 and 85 have been added. Claims 1-7, 9, 12-14, 21-24, 35, 39-41, 44-46, and 51-85 are currently pending.
4. In Paper No. 9, dated October 10, 2002, applicants elected a cellulose derivative for species A, BHT for species B, methylparaben for species C, and clobetasol for species D without traverse.
5. Claims 52, 53, 55-75 and 77-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
6. Claims 1-7, 9, 12-14, 21-24, 35, 39-41, 44-46, 51, 54, 76 and 83-85 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 103

7. Claims 1-7, 9, 12-14, 21-24, 35, 39-41, 44-46, 51, 54, 76 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Pat. No. 44 47 287 C1 in view of US Pat. No. 5,322,685 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the DE '287 does not teach adding cortiosteroids, specifically the elected species clobetasol, in the amounts claimed. The applicant argues that DE '287 only teaches adding the active ingredients in the amounts claimed if the active ingredient is water soluble, not water insoluble like clobetasol. However, DE '287 does specifically teach adding cortiosteroids to the transferosome. The reference does not specifically discuss a formulation that contains the cortiosteroids. However, the reference does teach that the amounts of the active ingredients and the carrier substances can be varied to produce a product with the optimum solubility and skin penetration characteristics. Therefore, the reference clearly teaches that the amount of the cortiosteroids in the transferosome can be varied in the course of producing the best product possible. Thus, a person of ordinary skill in the art would be motivated to modify the amount of corticosteroid in the transferosome. Such modifications would reasonably lead to the amount of cortiosteroid claimed by applicant.

Applicant discusses a specific embodiment of DE '287 where the active ingredients are water soluble. In this embodiment, the active ingredients are added in the amounts claimed by applicant. Applicant states that this embodiment teaches away from adding water insoluble ingredients in the amounts claimed by applicant. However, the reference makes it clear that the specific embodiment is directed towards water soluble active ingredients and that the parameters

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can be changed to accommodate water insoluble active ingredients (see page 10, second paragraph).

Applicant also argues that DE '287 is not properly combined with US '685 because they are nonanalogous prior art. However, US '685 addresses similar problems to those identified by DE '287. Both references are trying to solve problems associated with the topical administration of active agents. In hopes of solving these problems, DE '287 uses consistency builders and preservatives (see page 25) as does US '685 (see column 3, lines 52-61). Therefore, since the problems addressed by both references are the same, a person of ordinary skill in the art would reasonably look to the references to correct the problems.

8. No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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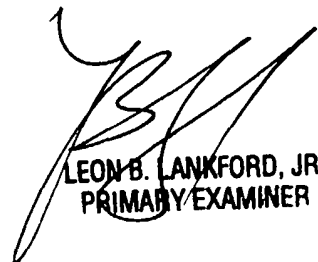
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
October 22, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER